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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,016	09/13/2000	Herman Van Mellaert	021565-078	1768

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/06/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,016

Applicant(s)

VAN MELLAERT ET AL

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) 20,21,23,25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-943)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

DETAILED ACTION

1. Applicant's election with traverse of Group III (claims 22, 24 and 26) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the Bt14-encoding the nucleic acid of Group III is obvious in light of the Bt14 protein of Group I, and vice versa. Applicant applies a similar argument to the restriction between the Bt15-encoding the nucleic acid of Group IV and the Bt15 protein of Group II.

This is not found persuasive. Applicant is reminded that a nucleic acid is not obvious over the protein that it encodes, and vice versa, and that the polynucleotide and the polypeptide are not linked because the polynucleotide encodes the polypeptide. The polypeptide is not directly made from the DNA molecule that encodes it. While the nucleic acid sequence may provide researchers the amino acid sequence of the initially-translated protein, it does not allow them to accurately predict properties of the protein like K_m , temperature maximum, or even molecular weight of the processed protein. Additionally, the protein can be isolated from the natural source and characterized in detail without knowledge of the DNA that encodes it, and in fact, many proteins were isolated years before DNA cloning and sequencing were possible. Thus, a nucleic acid is **not** obvious over the protein that it encodes, and vice versa.

The requirement is still deemed proper and is therefore made FINAL.

2. The draftsman has approved the drawings as submitted.
3. The disclosure is objected to because it is missing the Brief Description of the Drawings: See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 is required.
4. This application contains sequence disclosures that are encompassed by the definitions for

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nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from pg 26 (the bt4 gene) and pg 27 (the bt15 gene). It is also noted that the specification provides no sequence for the Bt14 gene.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set for in this Office action will be held to be non-responsive.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 22 is indefinite for being dependent upon a non-elected claim.

Claim 24 lacks antecedent basis for the limitation "the DNA of claim 22" as claim 22 is drawn to an isolated DNA sequence.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Brizzard et al (1988, Nuc. Acids Res. 16:4168-4169).

Brizzard et al teach a nucleic acid encoding cryA4, which is Bt14 in the nomenclature of the instant application (see pg 28, paragraph 1 of the specification).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 22, 24 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 22 of U.S. Patent No. 6,172,281.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated DNA encoding Bt14 of the instant claims is essential to the method of transforming plants with at least two nucleic acids, one of which encodes Bt14 and the transgenic plants thereby obtained, of the issued patent. Thus, the instantly claimed DNA is obvious in view of the claims of the issued patent. Additionally, because the Bt14 protein is produced in the plants

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of the issued patent, a chimeric gene comprising a nucleic acid encoding Bt14 operably linked to a promoter that can direct expression in plant cells must have been used, making the DNA molecule of claim 24 of the instant application obvious.

11. Claims 22, 24 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 14-15 of U.S. Patent No. 5,866,784.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the plants of the issued patent have been transformed with at least two nucleic acids, one of which encodes Bt14; thus, the plants of the instant application, which have been transformed with at a nucleic acid encoding Bt14, are obvious. Additionally, because the Bt14 protein is produced in the plants of the issued patent, a chimeric gene comprising a nucleic acid encoding Bt14 operably linked to a promoter that can direct expression in plant cells must have been used, making the DNA molecule of claims 22 and 24 of the instant application obvious.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
July 25, 2002



AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
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